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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,110	04/05/2001	Elizabeth A. Wang	CIBT-P03-031	7778

28120 7590 11/03/2003

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BOSTON, MA 02110-2624

EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/03/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,110

Applicant(s)

WANG, ELIZABETH A.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63 and 65-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63, 65-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This office action is in response to Paper No: 17, received 4/9/03, in which applicant cancelled claim 64 and amended claims 63, 65, and 67.

Claims 63, and 65-68 are pending.

Claim Rejections - 35 USC § 102

Claims 63 and 68 stand rejected as being anticipated under 35 U.S.C. 102(a) by Ingham (USPN 5,844,079) for the reasons set forth in the previous office action.

Applicant's arguments have been carefully considered but were not found persuasive.

Applicant contends that Ingham fails to satisfy the criteria for anticipating applicant's invention nor is the claimed subject matter obvious in view of the teachings of Ingham. The examiner disagrees. The claimed invention is drawn to a preparation comprising a sonic hedgehog polypeptide sequence in which the polypeptide is formulated for topical application to epithelial tissue.

Ingham teaches hedgehog related genes that generate and/or maintain an array of different vertebrate tissue both *in vitro* and *in vivo*, see abstract. Ingham discloses a preferred embodiment, sonic hedgehog polypeptide, column 3, lines 45-46 and column 170, claim 6. Ingham teaches the Shh polypeptide can comprise a fragment of at least 50, 100 or 150 amino acids in length, column 3, lines 57-58 and column 172, claims 29, 30, and 31. Ingham discloses hedgehog polypeptides which include Shh sequences corresponding approximately to the natural

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proteolytic fragments of the hedgehog proteins, such as from about Cys-24 through Glu-188, or from about Asn-189 through Ala-475 of the human Shh protein, or analogous fragments thereto, column 3, lines 59-64. Ingham teaches a method of introducing exogenous hedgehog polypeptide at the site of treatment, which is topical, column 52, lines 42-45. Absent some evidence to the contrary, the topical treatment disclosed by Ingham would inherently be used for epithelial tissue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 63, and 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ingham (USPN 5,844,079).

The claimed invention is drawn to a preparation comprising a sonic hedgehog polypeptide sequence in which the polypeptide is formulated for topical application to epithelial tissue.

Ingham teaches hedgehog related genes that generate and/or maintain an array of different vertebrate tissue both *in vitro* and *in vivo*, see abstract. Ingham discloses a preferred

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embodiment, sonic hedgehog polypeptide, column 3, lines 45-46 and column 170, claim 6.

Ingham teaches a sonic hedgehog polypeptide which fragment has an approximate molecular weight of 19kd, see column 171, claims 13 and 14. Ingham teaches the Shh polypeptide can comprise a fragment of at least 50, 100 or 150 amino acids in length, column 3, lines 57-58 and column 172, claims 29, 30, and 31. Ingham discloses hedgehog polypeptides which include Shh sequences corresponding approximately to the natural proteolytic fragments of the hedgehog proteins, such as from about Cys-24 through Glu-188, or from about Asn-189 through Ala-475 of the human Shh protein, or analogous fragments thereto, column 3, lines 59-64. Ingham teaches a method of introducing exogenous hedgehog polypeptide at the site of treatment, which is topical, column 52, lines 42-45. Absent some evidence to the contrary, the topical treatment disclosed by Ingham would inherently be used for epithelial tissue. Ingham teaches the hedgehog amino acid sequence is encoded by a naturally occurring hedgehog gene of a human, see column 172, claim 41.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the disclosure from Ingham to arrive at the invention in the instant application. Ingham teaches that the present invention can be utilized to generate an array of different vertebrate tissue both invitro and in vivo (see abstract).

Conclusion

All claims are rejected.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703)305-4243. The examiner can normally be reached on Monday-Friday from 5:30am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

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RT

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10/29/03

RT

A handwritten signature in black ink, appearing to be "CR Tate", written in a cursive, stylized manner.

CHRISTOPHER R. TATE
PRIMARY EXAMINER